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FROM: Robert Stadler, Shannon Nelson, and Lee Stylos

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SUBJECT: COMPARISON OF SEA AND SURFACE ECG FOR DETECTION
            OF CARDIAC ISCHEMIA.

I. EXECUTIVE SUMMARY

Cardiac ischemia is commonly diagnosed by searching for deviations of the ST segment from the isoelectric baseline. We hypothesized that the pseudo-ECG obtained by the subcutaneous electrode array (SEA) may contain similar ST segment changes during ischemia. To test this hypothesis, surface ECG (leads I, II, and V6) and SEA signals were obtained simultaneously in 20 patients during percutaneous transluminal coronary angioplasty (PTCA). The surface ECG and SEA signals were processed by the same algorithm to monitor changes in the ST segment that resulted from PTCA balloon inflation.

The overall sensitivity and positive predictivity of ST changes for detection of PTCA inflations were equivalent for the surface ECG and SEA. When individual inflations were analyzed, those that caused ST changes in the surface ECG but not in the SEA tended to result in inferior (i.e. right sided) ischemia. Conversely, inflations that caused ST changes in the SEA but not in the surface ECG tended to result in anterior (i.e. left sided) ischemia. The increased sensitivity of the SEA to left sided ischemia can be explained by the proximity of the SEA electrodes to the anterior and lateral aspect of the chest.

II. METHODS

Twenty patients (13 male, 7 female, age 60.5 +/- 13.4 (mean +/- STD) years, weight 184.6 +/- 42.4 pounds) who experienced PTCA to alleviate cardiac ischemia were selected for this study. To obtain a representative sample of the cardiac ischemia population, selection was based only on consent.

The standard electrocardiographic leads I, II, and V6 were obtained throughout the procedure and were stored on digital tape at 250 Hz and 16 bits of resolution. The choice of ECG leads was limited by the need to avoid fluoroscopic interference from the ECG electrodes. A device containing a subcutaneous electrode array (SEA) was consistently positioned on the skin in the left subclavicular region, in the first intercostal space and just medial to the mid-clavicular line. The device was held in place with a Tegaderm patch, and the skin in contact with the device was prepared in advance by cleaning with a mild abrasive. The SEA device consisted of 4 electrodes at the corners of a rectangle spanning 32 by 24 mm (see Figure 1). Internal differential amplifiers provided a gain of 1000 for three outputs: the differential of each pair of electrodes measured relative to a common ground electrode (i.e., A-B, B-C, and A-C, all relative to the common ground electrode D). The SEA outputs were stored on digital tape throughout the procedure at 250 Hz and 16 bits of resolution. The times and locations of PTCA balloon inflations were recorded during the procedure.

The myocardial region whose perfusion was affected by each balloon inflation was determined by review of angiographic records. The locations were categorized as "anterior", "lateral", "inferior", and "posterior". The vast majority of the myocardial regions were described as a combination of multiple categories (i.e., anterior/lateral, or inferior/lateral).

The three ECG and the three SEA signals were processed off-line by the same algorithm for ST segment analysis. For each subject, one of the six signals was selected for detection of R waves so that the location of R waves was consistent for analysis of the 6 signals. The processing of each signal involved beat-by-beat measurement of the ST segment at three locations, and comparison of the average ST segment level to that of the isoelectric point, obtained between the P wave and QRS complex. The absolute value of the difference between the ST segment and isoelectric point was then bandpass filtered. The lowpass filter removed beat-to-beat variations in the ST segment caused by noise and the highpass filter removed slow, nonischemic drifts of the ST segment. The result of the bandpass filtering was normalized by dividing by the R-wave amplitude. This result, expressed as a percentage of the R-wave amplitude, is called the "ischemia parameter".

The ischemia parameters were then compared with the timing of PTCA balloon inflations. A variety of threshold values for the ischemia parameters were used to obtain a receiver operating characteristic (ROC) curve for detection of balloon inflations. For each threshold value, the ischemia parameter was first converted to a binary signal, 1 for suprathreshold segments and 0 for subthreshold segments. The binary ischemia

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parameter and binary balloon inflation signals were then compared using the following rules:

SENSITIVITY (defined as the fraction of candidate balloon inflations that resulted in a suprathreshold ischemia parameter):

- The ischemia parameter must have passed above threshold between the beginning of the inflation and 60 seconds after the end of the inflation in order to be counted as a detection.
- If the ischemia parameter was suprathreshold at the onset of a balloon inflation, the candidate inflation was disqualified.
- Balloon inflations less than 25 seconds in duration were disqualified.

POSITIVE PREDICTIVITY (defined as the fraction of candidate suprathreshold ischemia parameter episodes that were associated with a balloon inflation):

- The start of a suprathreshold episode must have occurred between the beginning of the balloon inflation and 60 seconds after the end of an inflation to be counted as a detection.
- Suprathreshold episodes that were less than 15 seconds apart were combined into a single suprathreshold episode.
- If more than one suprathreshold episode was associated with a single balloon inflation, all but one of the suprathreshold episodes were disqualified. Therefore, multiple detections of the same balloon inflation were not allowed.

Thus, for each of the 3 ECG and 3 SEA signals and for each of the thresholds, a sensitivity and positive predictivity were calculated. Similar calculations were conducted to determine the performance of groups of signals (e.g., a combination of ECG leads I, II, and V6), by comparing the union of the individual binary (sub/supra-threshold) ischemia parameters to the binary balloon inflation signal. In this way, the overall detection of the ECG was compared with that of the SEA. Statistical comparisons of ROC's were obtained by bootstraping distributions of sensitivities and positive predictivities.

III. RESULTS AND DISCUSSION

The ROCs of single ECG leads for detecting the balloon inflations are presented in Figure 2. Similarly, the ROCs of single SEA leads are presented in Figure 3. The 3 ECG leads and the three SEA leads demonstrated similar performance. Figure 4 shows that the performance of two SEA leads in combination was the same as the performance of all three SEA leads in combination. This result follows from the fact that the third SEA lead is a linear combination of the other two, since they share electrodes. The only independent aspect of the third SEA signal is the random noise introduced by the amplifier. Therefore, the SEA was completely represented by a combination of leads 1 and 2.

The overall performances of the three ECG leads and the two SEA leads are compared in Figure 5. The horizontal and vertical bars denote standard deviations in

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sensitivity and positive predictivitiy, respectively. Clearly, there is no detectable difference in performance between the ECG and SEA. Although the overall performances are equivalent, the SEA and ECG often disagreed on the detection of individual balloon inflations. Table 1 contains lists of the regions of ischemia that produced suprathreshold ST changes in one set of leads but not in the other.

Table 1: A comparison of the ischemic regions that resulted in disparate ST changes in ECG and SEA.

Detected by ECG but not by SEA	Detected by SEA but not by ECG
inferior/lateral	anterior/lateral
inferior/lateral	anterior/lateral
posterior/lateral	inferior/posterior/lateral
inferior	lateral
inferior/lateral	anterior
posterior/lateral	inferior/anterior/lateral
anterior/lateral	anterior
inferior/lateral	
inferior/posterior/lateral	
inferior/lateral	
anterior	

Table 1 suggests that the SEA was more sensitive to anterior ischemia and the ECG was more sensitive to inferior ischemia. This result can be explained by the location of the SEA electrodes. Because the SEA electrodes have such a small span relative to the ECG electrodes, the SEA pseudo-ECG will present a "weighted" picture of cardiac electrical activity. Electrical activity in myocardium that is closer to the SEA will have a greater influence on the pseudo-ECG than electrical activity from distant myocardium. This statement is supported by the distributed dipole model (e.g., Circ. 1969; 40: 687-696) and by solid angle theory (e.g., Prog. Cardiovasc. Dis. 1977; 19: 431-457).

Figures 6 and 7 are the strongest examples of disagreement between the ECG and SEA. Each figure shows the 3 ECG and 3 SEA ischemia parameters during a PTCA procedure. The shaded regions are the times of balloon inflation. In Figure 6, the PTCA balloon was inflated in the mid-LAD (i.e., causing anterior ischemia). The SEA signals show a dramatic response to these inflations, while the ECG signals are only mildly effected. In contrast, Figure 7 shows a dramatic response of the ECG leads to occlusion of the PDA (i.e., causing inferior ischemia) while the SEA leads are only mildly effected.

The overall performance of the ECG and SEA in Figures 2-5 may be lower than expected. Certainly, the performance depends on the selection of detection rules which were detailed above. Because the purpose of this study was to compare the performance of two lead systems, the absolute performance is not important. Equal application of the detection rules to the SEA and ECG is important. It is interesting to note that only 70 to 80% of PTCA inflations cause a detectable ST change, even when the distal tip of the

PTCA guidewire is used as a lead electrode (Circ. 1986; 74: 330-339. Am Heart J 1992; 124: 337-341.)

IV. CONCLUSIONS

The pseudo-ECG obtained from an SEA demonstrated similar overall performance to a three lead surface ECG for detecting ST changes due to PTCA. Although the overall performances were equivalent, the SEA and ECG often disagreed on individual balloon inflations. Where the two disagreed, the SEA was more sensitive to anterior ischemia while the ECG was more sensitive to inferior ischemia.

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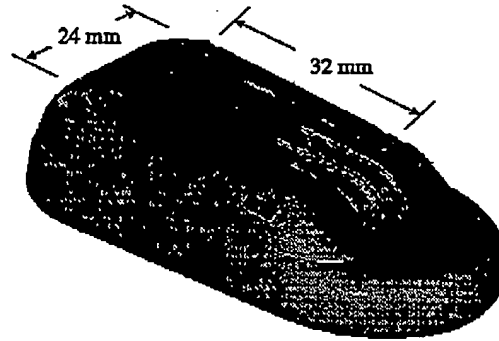
Figure 1: The SBA device. The 4 electrodes are at the corners of a rectangle with the indicated dimensions. The electrodes were coated with a conductive gel and placed on the surface of the skin.
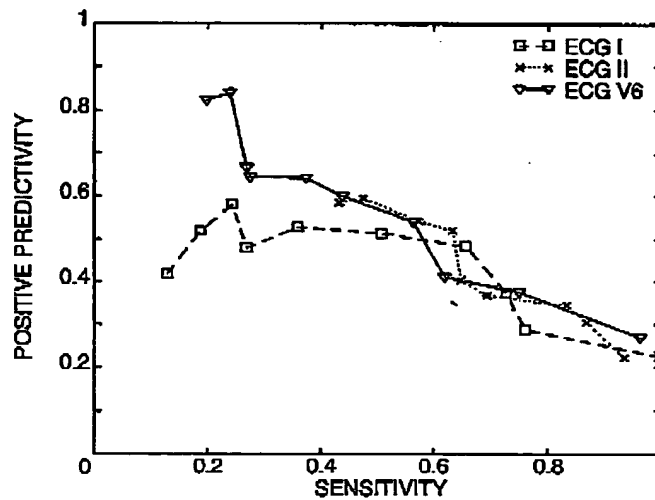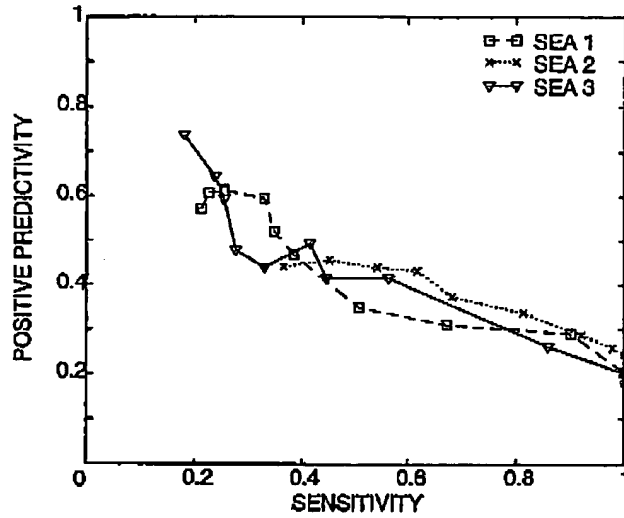

Figure 2: The performance of individual ECG leads for reporting ST changes as a result of balloon inflation. The threshold for ST change varies along the curves.

Figure 3: The performance of individual SEA leads for reporting ST changes as a result of balloon inflation. The threshold for ST change varies along the curves.
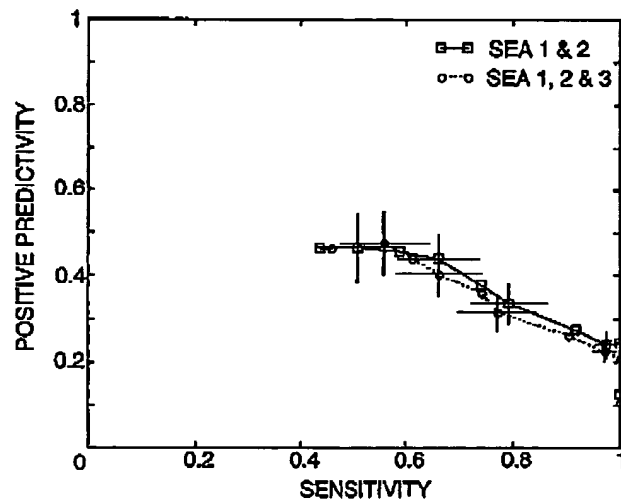

Figure 4: The performance of a combination of SEA leads 1 and 2 vs. that of SEA leads 1, 2 and 3. The horizontal and vertical bars are standard deviations.
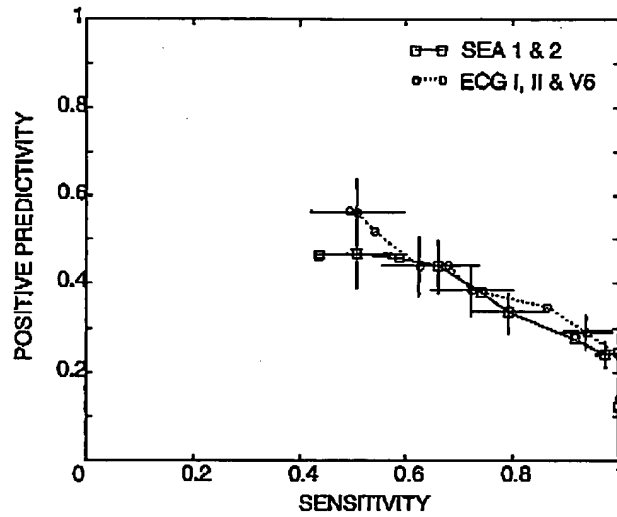
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Figure 5: The performance of a combination of SEA leads 1 and 2 vs. that of ECG leads I, II and V6. The horizontal and vertical bars are standard deviations.
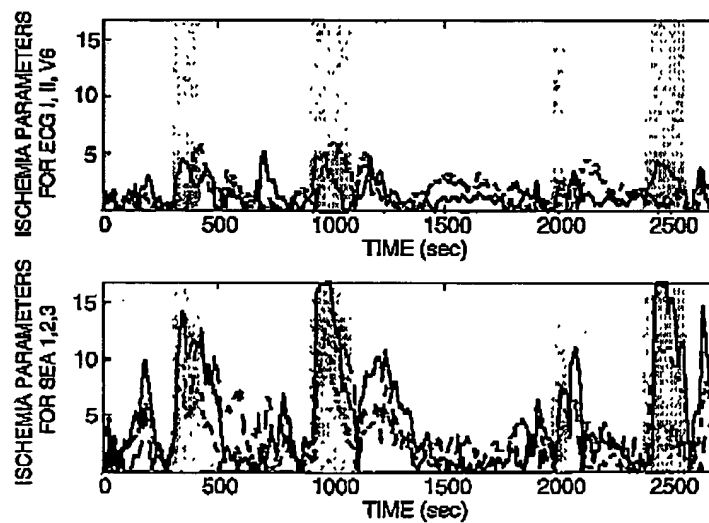
Figure 6: Ischemia parameters (ST deviation expressed as a percent of R wave amplitude) for the 3 ECG and 3 SEA leads during PTCA. The shaded regions indicate balloon inflation. The balloon was located in the mid-LAD.
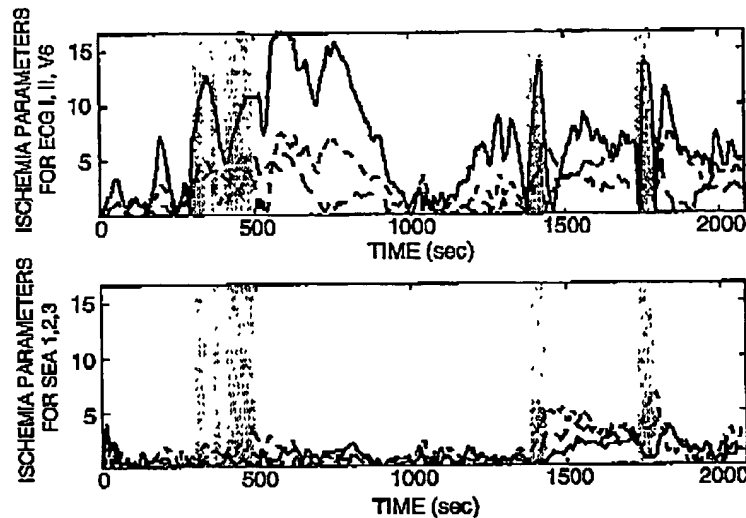
Figure 7: Ischemia parameters (ST deviation expressed as a percent of R wave amplitude) for the 3 ECG and 3 SEA leads during PTCA. The shaded regions indicate balloon inflation. The balloon was located in the PDA.

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